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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,680	07/20/2005	Maria Prat Quinones	09605.0003	4960

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EXAMINER	
CHU, YONG LIANG	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/510,680	PRAT QUINONES ET AL.	
	Examiner	Art Unit	
	Yong Chu	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 30-34* is/are pending in the application.

4a) Of the above claim(s) *11,21,22,25,30 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-20,23,24,26 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. Spain 200200889.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/25/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

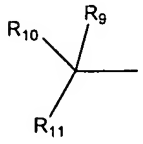
Claims 27-29 are cancelled by amendment filed on 8 October 2004. Claims 1-26, 30, 32 and 33 are amended by amendment filed on 8 October 2004. Claim 34 is added by amendment filed on 8 October 2004. Therefore, claims 1-26, and 30-34 are currently pending in the instant application.

Priority

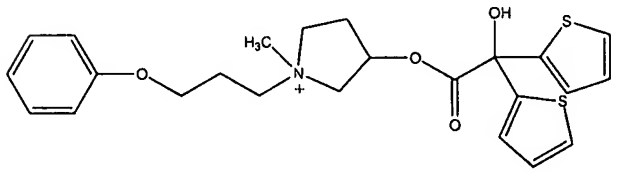
This application is a 371 of PCT/EP03/03786, filed on 11 April 2003. Applicants claim the benefit of for Spain Patent Application 2002-00889 filed on 16 April 2002, under 35 U.S.C. §119(a-d).

Response to Lack of Unity

The response to the restriction request with provisionally election of Group III (e.g. claims 1-10, 12-20, 23-24 (in part wherein **A** is –O-, -S-, -S(O)-, and $-S(O)_2-$; **D** is



wherein $\mathbf{R^9}$-$\mathbf{R^{11}}$ defined according to claim 1), 26, and 32-34) and species of

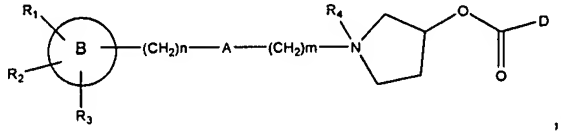


with traverse by Applicants' representative, Carlos M. Tellez dated on 3 April 2006, has been considered.

Applicant's arguments on page 7-8 of the Remark are considered, but not persuasive. Please refer to the Office Action dated on 1 February 2006. This restriction requirement is made final.

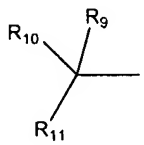
Status of the Claims

The scope of the invention of the elected subject matter is as follows:

Compounds of formula (I), 

, depicted in claim 1, wherein:

A is –O-, -S-, -S(O)-, and $-S(O)_2-$;

D is 

wherein $\mathbf{R^9}$-$\mathbf{R^{11}}$ defined according to claim 1;

B represents a group chosen from phenyl, naphthalenyl, benzo[1,3]dioxolyl, a 5 to 10-membered hetero-aromatic group, ...;

The remaining substituents are defined in claim 1.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-10, 12-20, 23-24, 26, and 32-34 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would

not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Therefore, Claims 1-10, 12-20, 23-24, 26, and 32-34 are ready to be examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12-20, 23-24, 26, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because the improper use of proviso, which does not clearly point out which compounds or compositions are regarded as the invention, and why certain groups are not included from the generic claim.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "a compound effective in the treatment of a respiratory, urological or gastrointestinal disease or disorder" is not defined in the Specification.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Specification fails to point out the compounds such as a ß2 agonist, steroid, antiallergic drug. ß2 agonist is indefinite.

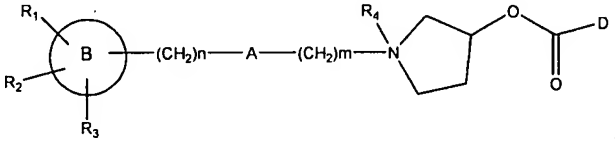
Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "admixture" is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

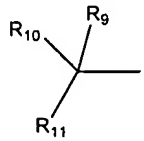
> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 10, 14, 26, and 32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta *et al.*, WO2002-IB5590.

Applicants' instant elected invention in claims 1-4, 10, 14, and 26 teaches a compound of formula (I) 

, depicted in claim 1, wherein:

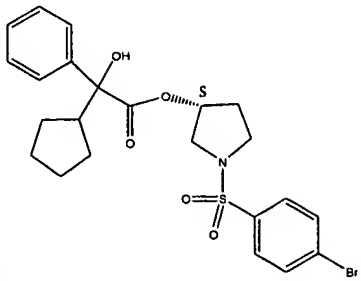
A is –O-, -S-, -S(O)-, and $-S(O)_2-$;

D is 

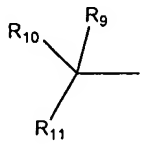
wherein $\mathbf{R^9}$-$\mathbf{R^{11}}$ defined according to claim 1;

B represents a group chosen from phenyl, naphthalenyl, benzo[1,3]dioxolyl, a 5 to 10-membered hetero-aromaticgroup, ...;

The remaining substituents are defined in claim 1.

Mehta et al. teach a specific compound 14  of page 12, read on the instant claims 1 wherein:

A is $-S(O)_2-$;

D is  wherein $\mathbf{R^9}$ is phenyl, $\mathbf{R^{10}}$ is cyclopentane, and $\mathbf{R^{11}}$ is hydroxyl;

B is phenyl;

$\mathbf{R^1}$, $\mathbf{R^2}$ is H, and $\mathbf{R^3}$ is bromide;

the configuration at 3-position of pyrrolidine is S.

Claim Rejections - 35 USC § 103

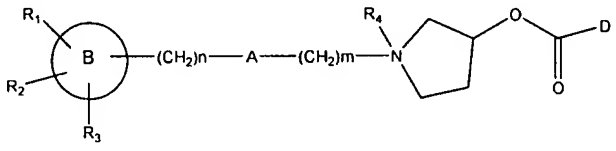
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

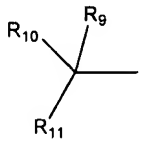
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 12 are rejected under 35 U.S.C. 103 (a) as unpatentable over Mehta et al., WO2002-IB5590.

Applicants instant elected invention in claims 5 and 12 teach compounds of formula (I), 

, depicted in claim 1, wherein:

A is –O-, -S-, -S(O)-, and $-S(O)_2-$;

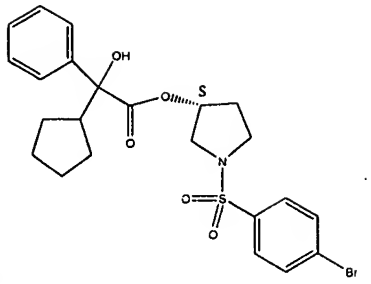
D is 

wherein $\mathbf{R^9}$-$\mathbf{R^{11}}$ defined according to claim 1;

B represents a group chosen from phenyl, naphthalenyl, benzo[1,3]dioxolyl, a 5 to 10-membered hetero-aromaticgroup, ...;

The remaining substituents are defined in claim 1.

Determination of the scope and content of the prior art (MPEP §2141.01)



Mehta et al. teach a specific compound of formula,

Of compound 14 on page 12 of the Specification. Mehta et al. does not teach a compound wherein X- anion is Cl-, Br-, CF_3COO-, and does not teach $\mathbf{R^3}$ is F, Cl. However, the prior art does teach the compound and its pharmaceutically acceptable salts, which is Cl^-, or Br^-, known to one of skilled in the art.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Mehta et al. and the instantly claimed compounds, is that Br of the compounds of Cameron et al. could be Cl or halogen of the instantly claimed compounds.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would have found the claimed compound prima facie obvious because it is well established that the substitution of Br for Cl or F, and pharmaceutical salts anions are Cl^-, Br^- on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lahr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963).

Conclusion

No claims are allowed.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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